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Exhibit R-2, RDT&E Budget Item Justification: PB 2012 Chemical and Biological Defense Program **DATE:** February 2011

APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>				R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>							
COST (\$ in Millions)	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost
Total Program Element	233.443	169.287	219.873	-	219.873	217.812	204.080	181.892	224.254	Continuing	Continuing
CB2: <i>CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	110.937	88.897	97.774	-	97.774	94.721	89.677	90.823	108.941	Continuing	Continuing
CI2: <i>CONGRESSIONAL INTEREST ITEMS (APPLIED RESEARCH)</i>	27.186	-	-	-	-	-	-	-	-	0.000	27.186
TB2: <i>MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	54.858	43.858	84.747	-	84.747	85.493	76.011	52.527	75.583	Continuing	Continuing
TC2: <i>MEDICAL CHEMICAL DEFENSE (APPLIED RESEARCH)</i>	38.644	33.648	36.546	-	36.546	36.993	37.789	38.163	39.395	Continuing	Continuing
TR2: <i>MEDICAL RADIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	1.818	2.884	0.806	-	0.806	0.605	0.603	0.379	0.335	Continuing	Continuing

A. Mission Description and Budget Item Justification

Funding under this program element (PE) sustains a robust defense program, which both reduces the danger of a chemical, biological, or radiological (CBR) attack and enables U.S. forces to survive, and continue operations in a CBR environment. The medical program focuses on development of antidotes, drug treatments, casualty diagnosis, patient decontamination and medical technologies management. In the physical sciences area, the emphasis is on continuing improvements in CB defense materiel, including contamination avoidance, decontamination, and protection technologies. Research efforts are planned to be initiated for CB defense technologies that will result from a strategic approach of converging nanotechnology, biotechnology, information technology and cognitive science. This PE also provides for applied research in the areas of real-time sensing and immediate biological countermeasures. The work in this PE is consistent with the Chemical Biological Defense Program Research Development and Acquisition (RDA) Plan. Efforts under this PE transition to or provide risk reduction for Advanced Technology Development (PE: 0603384BP), Advanced Component Development and Prototypes (PE: 0603884BP) and System Development and Demonstration (PE: 0604384BP).

BA2 reductions in support of the DoD Efficiency Initiatives for FY12 include: Service Support Contracts reduced (-\$7.626M).

Efforts included in this Program Element address non-system specific development, directed toward military needs.

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APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE
0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>	PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>

B. Program Change Summary (\$ in Millions)	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total
Previous President's Budget	224.830	169.287	189.340	-	189.340
Current President's Budget	233.443	169.287	219.873	-	219.873
Total Adjustments	8.613	-	30.533	-	30.533
• Congressional General Reductions		-			
• Congressional Directed Reductions		-			
• Congressional Rescissions	-	-			
• Congressional Adds		-			
• Congressional Directed Transfers		-			
• Reprogrammings	1.076	-			
• SBIR/STTR Transfer	-2.749	-			
• Other Adjustments	10.286	-	30.533	-	30.533

Congressional Add Details (\$ in Millions, and Includes General Reductions)

Project: CI2: *CONGRESSIONAL INTEREST ITEMS (APPLIED RESEARCH)*

Congressional Add: <i>Chem/Bio IR Detection System</i>	1.892	-
Congressional Add: <i>HyperAcute Vaccine Development</i>	3.585	-
Congressional Add: <i>Chemical Agent Fate Appropriate Response Tool</i>	1.593	-
Congressional Add: <i>Botulinum Neurotoxin Research</i>	1.992	-
Congressional Add: <i>Miniaturized Chemical Detector for Chemical Warfare Protection (ChemPen)</i>	1.593	-
Congressional Add: <i>Chemical and Biological Resistant Clothing</i>	1.593	-
Congressional Add: <i>Botulinum Toxin Treatment Therapy</i>	0.797	-
Congressional Add: <i>PaintShield for Protecting People from Microbial Threats</i>	1.992	-
Congressional Add: <i>Mismatch Repair Derived Antibody Medicines to Treat Staphylococcus-derived Bioweapons</i>	0.996	-
Congressional Add: <i>Advanced Development of Antiviral Prophylaxis and Therapeutics</i>	2.987	-
Congressional Add: <i>Potent Human Monocolonal Antibodies Against BoNT, A, B and E (Botulinum Neurotoxins) Suited for Mass Production and Treatment of Large Populations</i>	0.996	-
Congressional Add: <i>Countermeasures to Chemical and Biological Controls-Rapid Response</i>	2.788	-
Congressional Add: <i>MEMS Sensors for Real-time Sensing of Weaponized Pathogens</i>	1.992	-
Congressional Add: <i>Mobile Rapid Response Prototype</i>	2.390	-

FY 2010	FY 2011
1.892	-
3.585	-
1.593	-
1.992	-
1.593	-
1.593	-
0.797	-
1.992	-
0.996	-
2.987	-
0.996	-
2.788	-
1.992	-
2.390	-

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Congressional Add Details (\$ in Millions, and Includes General Reductions)		FY 2010	FY 2011
Congressional Add Subtotals for Project: CI2		27.186	-
Congressional Add Totals for all Projects		27.186	-
<u>Change Summary Explanation</u> Funding: FY10 - Adjustments less than 10% of total program. FY12 - Program realignments to support high priority CBDP and DoD program initiatives (+\$1.069K CB2; +\$36,958K TB2; +\$1,541K TC2; -\$1,071K TR2); Economic assumptions (-\$148K CB2; -\$134K TB2; -\$55K TC2; -\$1K TB2); Reductions to Service Support Contracts in support of the DoD Efficiency Initiatives (-\$3,389K CB2; -\$2,943K TB2; -\$1,267K TC2; -\$27K TR2). Schedule: N/A Technical: N/A			

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program **DATE:** February 2011

APPROPRIATION/BUDGET ACTIVITY				R-1 ITEM NOMENCLATURE				PROJECT			
0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>				PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>				CB2: <i>CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>			
COST (\$ in Millions)	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost
CB2: <i>CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	110.937	88.897	97.774	-	97.774	94.721	89.677	90.823	108.941	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project (CB2) provides physical applied research to develop future, multi-disciplinary, multi-functional capabilities in life sciences, physical sciences, environmental sciences, mathematics, cognitive sciences, and engineering. Efforts in this project support the seamless integration of state-of-the-art-technologies into a collection of systems across the spectrum of capabilities required to support chemical and biological defense missions, including specific research to develop defensive capabilities against non-traditional agents (NTAs). Starting in FY11, all NTA-dedicated research will be re-aligned into specific capability areas within this project in order to ensure a focused effort on this high priority area. Capability areas in this project include: detection; detection for NTAs; information systems technology; protection/hazard mitigation; protection/hazard mitigation for NTAs; threat agent science; and threat agent science for NTAs. Detection focuses on developing technologies for standoff and point detection and identification of chemical and biological agents. Information systems technology focuses on advanced warning and reporting, hazard prediction and assessment, simulation analysis and planning, and systems performance modeling. Protection and hazard mitigation focuses on providing technologies that protect and reduce the chemical/biological threat or hazard to the Warfighter, weapons platforms, and structures. Threat agent science is devoted to characterizing threat agents and the hazards they present in terms of agent fate in the environment, toxicology, pathogenicity and the development of simulants, especially with regard to NTAs. This project focuses on horizontal integration of CB defensive technologies in support of the Joint Services.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2010	FY 2011	FY 2012
Title: 1) Protection & Hazard Mitigation Description: Innovative Systems Concepts and Analysis: Development and systems analysis of novel system concepts for chemical and biological protection of occupants of buildings and platforms that integrates emerging technologies. FY 2010 Accomplishments: Investigated alternate system solutions and technologies for Collective Protection (COLPRO). Technologies included micro fine detoxifying aerosol fogs to facilitate entry and mitigate cross contamination into the COLPRO system, internal self-detoxifying surfaces for walls and ductwork, expedient retrofit kits, self-detoxifying and expedient strippable coatings, rapid isolation and purge schemes, and novel and innovative air flow and re-circulation schemes. FY 2012 Plans: Continuation of Innovative Systems Concepts and Analysis projects from FY10. Transition research effort "Reactive Airlock for Armored Vehicles, Shipboard and Shelter Applications."	1.185	-	0.345
Title: 2) Protection & Hazard Mitigation	7.081	1.546	1.829

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
<p>Description: Lightweight Integrated Fabric: Development of lightweight chemical and biological protective textiles that can be used as an integrated combat duty uniform.</p> <p>FY 2010 Accomplishments: Supported assessment of integrated fabric concurrent with the Individual Protection Advanced Technology Demonstration (IP Demo - see Budget Activity 3, Project TT3, Experiment and Technology Demonstrations), which supports the Uniform Integrated Protection Ensemble (UIPE) and incorporated lessons into further development of integrated fabric. Continued work on fabric residual life indicators and agent indicators that can be network enabled. Continued development of polymer membranes with permeability properties electrically controlled. Continued development of novel sorbents leap-ahead improvements over activated carbon technologies. Continued development work on ultra light and tactile barrier materials for gloves and boots. Continued development and scaling of nanofiber/textile production technologies. Continued fabrication and testing of prototype integrated fabrics to determine protection, mechanical properties, and heat transfer characteristics. Continued use of computational methods for assessment and refinement of prototypes. Continued ensemble design conceptual work based on lessons gathered in the human performance project. Continued support of fabrication of prototype ensembles for evaluation and demonstration.</p> <p>FY 2011 Plans: Incorporate lessons learned from the Individual Protection Advanced Technology Demonstration (see TT3 E&TD), which will support the Lightweight CB Ensemble (LCBE), and incorporate lessons into further development of integrated fabric. Complete work on network-enabled fabric agent indicators. Continue development work on ultra light and tactile barrier materials for gloves and boots and continue fabrication and testing of prototype integrated fabrics to determine protection, mechanical properties, and heat transfer characteristics. Continue development and scaling of nanofiber/textile production technologies for transition to Uniform Integrated Protection Ensemble (UIPE) and/or Joint Service Lightweight Integrated Suit Technology (JSLIST) program. Continue use of computational methods for assessment and refinement of prototypes. Continue development of ensemble design conceptual work based on lessons gathered in the human performance project for transition to UIPE/JSLIST.</p> <p>FY 2012 Plans: Continue development work, fabrication, and testing of prototype integrated fabrics to determine protection, mechanical properties, and comfort characteristics (such as heat and water vapor transfer properties). Continue use of computational methods to assess and refine prototypes; develop improved thermal modeling simulations. Develop and scale an advanced adsorbent nanofiber/textile production technology and/or a "smart material" technology for possible transition to a UIPE program. Continue development of ensemble design conceptual work based on the lessons gathered in the human performance projects for transition to UIPE/JSLIST.</p>					
Title: 3) Protection & Hazard Mitigation			6.354	3.528	4.005

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
<p>Description: Low-Resistance, Low-Profile Filtration: Development and integration of novel filtration media into a lightweight, low-profile, and low-burden individual protective filter, which has enhanced performance against a broader range of challenges that includes toxic industrial chemicals.</p> <p>FY 2010 Accomplishments: Supported assessment of integrated fabric concurrent with the Individual Protection Advanced Technology Demonstration, which supports the Uniform Integrated Protective Ensemble (UIPE), and incorporated lessons into further development of low resistance/profile filtration. Continued project to develop the next generation filter that provides individual protection from chemical and biological (CB) agents, Toxic Industrial Chemicals (TICs) and Non Traditional Agents (NTAs). Integrated metal-organic frameworks and other novel adsorbent into "breadboard" prototypes. Integrated nanofiber High Efficiency Particulate Air (HEPA) filters into "breadboard" prototypes. Continued reactive hybrid approaches for individual protection filtration. Developed and fabricated initial prototypes and evaluated performance. Initiated prototype work for collective protection filtration in support of advanced development programs such as the Joint Expeditionary Collective Protection (JECp) and supported collective protection in vehicular/platform systems.</p> <p>FY 2011 Plans: Incorporate lessons learned from the Individual Protection Advanced Technology Demonstration, which will support the Uniform Integrated Protective Ensemble (UIPE), and incorporate lessons into further development of low resistance/profile filtration. Continue project to develop the next generation filter for individual protection from CB agents, TICs and NTAs. Integrate metal-organic frameworks and other novel adsorbent into "breadboard" prototypes. Integrate nanofiber HEPA filters into breadboard prototypes. Continue reactive hybrid approaches for individual protection filtration and evaluate performance. As a result of the IP Demo, refine prototype concept filters to advanced development programs such as the Joint Service General Purpose Mask (JSGPM), Joint Service Aircrew Mask (JSAM), UIPE programs, improved media for collective protection filters in Joint Expeditionary Collective Protection (JECp), and in support of collective protection in vehicular/platform systems.</p> <p>FY 2012 Plans: Continue development of low resistance/profile filtration. Continue project to develop the next generation novel filtration media for individual protection from CB agents and TICs (NTAs are addressed in Protection & Hazard Mitigation NTA). Transition these technologies to the Joint Service General Purpose Mask (JSGPM) and Joint Service Aircrew Mask (JSAM) programs. Integrate metal-organic frameworks and other novel adsorbent into "system" prototypes. Integrate nanofiber HEPA filters into system prototypes. Continue reactive hybrid approaches for individual protection filtration and evaluate performance.</p>					
Title: 4) Protection & Hazard Mitigation			2.118	0.711	0.484

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
<p>Description: Human Performance Prediction and Assessment: Analysis and modeling of human performance in chemical and biological protective ensembles in order to determine design priorities and trade-offs.</p> <p>FY 2010 Accomplishments: Supported assessment of integrated fabric concurrent with the Individual Protection Advanced Technology Demonstration, which supports the Uniform Integrated Protective Ensemble (UIPE), and incorporated lessons into further development of human performance prediction and assessment. Continued refining human performance parameters for various Warfighter subgroups in the performance of their mission when CB protective systems are employed. Continued work to develop an overall comfort and performance model for CB protective equipment. Initiated anthropometric sizing study to support size tariff development.</p> <p>FY 2011 Plans: Incorporate lessons learned from the Individual Protection Advanced Technology Demonstration, which will support the Uniform Integrated Protective Ensemble (UIPE), and incorporate lessons into further development of human performance prediction and assessment. Complete human performance model for CB protective equipment. As a result of the IP Demo, transition model data and analysis to individual protection advanced development programs. Continue anthropometric sizing study to support size tariff development.</p> <p>FY 2012 Plans: Continue development of human performance prediction and assessment by investigating the interactive effects of competing burdens on human cognitive performance. Studies will be conducted to quantify the cumulative effects of the two primary factors researched to date: thermal burden (via moisture vapor transport rate) and breathing resistance. Transition data on Human Performance Assessment that will allow the prediction and design of individual protective gear.</p>					
<p>Title: 5) Protection & Hazard Mitigation</p> <p>Description: Low-Burden Air Purifying Respirator: Development and analysis of design alternatives for chemical and biological air-purifying respirators to provide enhanced protection with lower physiological burden and improved interface with mission equipment.</p> <p>FY 2010 Accomplishments: Supported assessment of integrated fabric concurrent with the Individual Protection Advanced Technology Demonstration, which supported the Uniform Integrated Protective Ensemble (UIPE), and incorporated lessons learned into further development of a low-burden air purifying respirator. Continued to define the key development parameters associated with respiratory protective systems and incorporated data and lessons from the human performance project. Continued integration analysis with</p>			2.115	2.590	2.591

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
ground Warfighter helmet systems. Completed integration work on the dual-cavity respirator. Continued to refine and fabricate prototypes and evaluate performance. FY 2011 Plans: Incorporate lessons learned from the Individual Protection Advanced Technology Demonstration, which will support the Uniform Integrated Protective Ensemble (UIPE), and incorporate lessons into further development of a low-burden air purifying respirator. Complete the assessment of the key development parameters associated with respiratory protective systems and incorporate data and lessons from the human performance project. Incorporate lessons learned from the IP Demonstration into protective mask prototypes. Complete integration analysis with ground Warfighter helmet systems. Continue to integrate work on the dual-cavity respirator concepts into the final design. FY 2012 Plans: Continue development of a low-burden air purifying respirator. Advanced concept CBRN technologies will be integrated within the confines of the Chem/Bio protection component of the Helmet Electronics and Display System - Upgradable Protection (HEADS-UP) Army Technology Objective (ATO) program, which has multi-service participation for ground applications. Various levels of comfort versus protection will be integrated into prototype helmets. Work will focus on revolutionary, innovative design concepts (such as a dual-cavity respirator) in the final design in order to support decisions to initiate future helmet/mask developmental programs.					
Title: 6) Protection & Hazard Mitigation Description: Logistically Sustainable Air Purification for Collective Protection: Development of chemical and biological air-purification alternative technologies that minimize or eliminate the need for expendable media within acceptable size, weight and power constraints. FY 2010 Accomplishments: Completed development and analysis of prototypes of energetic, reactive, media-less, air purification technologies that reduce size, weight, and lifecycle costs of removing chemical and biological agents and toxic industrial chemicals (TICs) from both make-up and re-circulation air in buildings, shelters, or platforms. Completed development of an acoustic fractionator that removes particulates down to the submicron level using standing sound waves. Continued development of a new air purification technology based on selective ionization and contaminant extraction. Completed development of a novel, low pressure drop, HEPA filter, which provides increased dust capacity and extended filter life through the use of irregularly shaped high surface area submicron fibers. FY 2011 Plans:			2.419	1.937	0.966

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
Continue development of reactive membrane and regenerative post treatment media technologies for applications in building protection and vehicular/platform systems for Major Defense Acquisition Programs (MDAP). FY 2012 Plans: Continue development of reactive membrane and regenerative post treatment media technologies for applications in building protection and vehicular/platform systems.					
Title: 7) Protection & Hazard Mitigation Description: General Purpose Formulations for Decontamination: Development and improvement of chemical and biological decontamination formulations that are compatible with the current family of decontamination systems. FY 2010 Accomplishments: Continued solid oxidant and green surfactant efforts resulting from alternative process research that emphasize dual-use technologies. Initiated focused enzymatic decontamination approaches. FY 2011 Plans: Complete development, testing and transition of solid oxidant and green surfactant to support advanced development programs such as the Hazard Mitigation for Material and Equipment Restoration (HaMMER) Advanced Technology Demonstration (see Budget Activity 3, Project TT3, Experiment & Technology Demonstrations), also known as the Decontamination Family of Systems Demonstration. Continue focused enzymatic decontamination development. FY 2012 Plans: Continue focused enzymatic decontamination development. Complete study and transition data on agent fate of contaminated human remains and transition to the Human Remains Decontamination System program.			1.956	2.830	1.561
Title: 8) Protection & Hazard Mitigation Description: Decontamination Family-of-Systems (DFoS): Development and analysis of non-traditional decontamination technologies and approaches which gain significantly improved effectiveness by complementary application. FY 2010 Accomplishments: Completed development of self-detoxifying coatings, agent disclosure spray efforts, and strippable coating efforts and transitioned products in advanced development programs such as the Hazard Mitigation for Material and Equipment Restoration (HaMMER) Advanced Technology Demonstration. Continued investigation of microwave interaction with coating embedded particles			2.677	4.348	5.012

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2010	FY 2011	FY 2012
and functionalities for directed energy decontamination. Completed work on functionalized photocatalytic materials. Initiated formulation development of a Decontamination Family of Systems that allowed optimized formulation adjustment at point-of-use. FY 2011 Plans: Develop data to define performance envelop of system components and transition to HaMMER. Initiate a study on impact of application methods of decontaminants to complex surfaces. FY 2012 Plans: Transition mature DFoS technologies including reactive coatings; continue developing other promising technologies. Continue the optimization of decontamination applicators. Continue investigation of microwave interaction with coating embedded particles and functionalities for directed energy decontamination. Coatings efforts will also examine durable and temporary coatings that pursue reactive and barrier options. Continue studies on effect of delivery and application methods on decontamination efficacy on complex surfaces.				
Title: 9) Protection & Hazard Mitigation Description: Smart Hazard Mitigation: Development of decontamination technologies that sense, respond (decontaminate) and signal in the presence of chemical and biological contamination. FY 2010 Accomplishments: Completed feasibility studies on the use of surface-modified nanoporous beads as encapsulation delivery devices for decontaminants. Continued development of molecular switches that respond and react to the presence of CB agents and signal results. Initiated development of rotaxane chemistry as artificial tunable G and V receptors that sense and react to chemical agents. FY 2011 Plans: Continue development of molecular switches that respond and react to the presence of CB agents and signal results. Continue development of rotaxane chemistry as artificial tunable G and V receptors that sense and react to chemical and biological agents. FY 2012 Plans: Continue development of molecular switches that respond and react to the presence of CB agents and signal results. Continue development of rotaxane chemistry as artificial tunable G and V receptors that sense and react to chemical and biological agents. Conduct comparative analysis/technology readiness assessment of smart system candidate technologies to select candidates for further development.		1.873	1.388	1.477
Title: 10) Protection and Hazard Mitigation		3.366	-	-

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
<p>Description: Novel Threat Agent Assessment and Methods: Focuses on Non-Traditional Agent hazard, permeation, and quantification of the hazard as it pertains to developing protective and hazard mitigation technologies. In FY11, all NTA efforts are re-aligned to Protection and Hazard Mitigation NTA capability area within this Project.</p> <p>FY 2010 Accomplishments: Initiated methodology development for assessment and quantification of (1) percutaneous hazards from permeation of liquid NTAs. Initiated methodology development for assessment and quantification, and (2) decontamination contact hazard residuals of NTAs. Baselined methodologies for current filtration, barrier materials, and textile effectiveness against NTAs. Continued efforts to assess and predict NTA performance on military chemical warfare agent (CWA) adsorbents.</p>					
<p>Title: 11) Protection and Hazard Mitigation NTA</p> <p>Description: NTA Air Purification: Study and assessment of filter technologies.</p> <p>FY 2011 Plans: Complete assessment of military carbon against NTAs, including performance when exposed to battlefield contaminants such as petroleum, oil, lubricants, and sweat. Develop and test novel materials to improve performance against NTAs. Provide results for upgrades into developmental programs.</p> <p>FY 2012 Plans: Continue development and testing of novel materials to improve performance against NTAs. Materials explored will include crystalline nano-porous framework materials, catalytic, nano-fibrous, and composite materials.</p>			-	2.280	1.024
<p>Title: 12) Protection & Hazard Mitigation NTA</p> <p>Description: NTA Percutaneous Protection: Study and assessment of protective technologies.</p> <p>FY 2011 Plans: Develop technologies to improve overall protective clothing performance against NTAs. Develop and assess improved ensemble closures and evaluate current individual protective (IP) barrier materials. Develop component aerosol test methods for performance standards of IP ensembles. Modify and verify material swatch test methods for liquid and aerosol for performance standards of IP materials. Develop breathable aerosol barrier materials and self-detoxifying fabrics. Develop and evaluate improved barrier materials for protective gloves and boots. Complete assessment of expedient approaches and skin barrier treatments. Develop and test performance enhancements that improve material agent resistance and garment closure performance.</p> <p>FY 2012 Plans:</p>			-	2.996	2.591

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
Continue development of technologies to improve overall protective clothing performance against NTAs. Perform component and system modeling in order to (1) evaluate and utilize aerosol-based closure testing; and (2) model aerosol transport within individual protective equipment ensembles. Design and test novel closures in accordance with modeling results/predictions. Fabricate prototype systems and then test/measure their aerosol performance.					
Title: 13) Protection & Hazard Mitigation NTA Description: NTA Decontamination: Study and assessment of decontamination technologies. FY 2011 Plans: Assess performance of current and developmental decontamination technologies against NTAs. Develop decontamination technologies and formulations that are optimized against NTAs. Modify and verify test procedures for NTAs. Develop and test decontamination formulations and system-of-systems approaches that improve performance against NTAs and manage process residuals. FY 2012 Plans: Continue development of decontamination technologies against NTAs. Continue to develop decontamination technologies and formulations that are optimized against NTAs. Continue development and test decontamination formulations and system-of-systems approaches that improve performance against NTAs and manage process residuals, including effluent control. Continue development of durable and temporary, reactive and barrier coatings to mitigate NTA contamination.			-	3.124	2.367
Title: 14) Threat Agent Science Description: Physiological Response: Delivers the scientific understanding and relevant estimates of the hazards posed to humans by exposure to chemical or biological agents. Toxicological and/or infectious-dose information supports developing and/or enhancing both operational risk and exposure guidelines; limits for detection and protection; goals for decontamination; and medical countermeasures. FY 2010 Accomplishments: Refined and standardized exposure and analytical methods for evaluation of percutaneous exposure to selected low volatility CWAs and high priority NTAs. Assessed established contact and inhalation hazard methodologies for applicability to next-generation chemical warfare agents and refined as evaluation indicates. Set milestones and began research on hazard assessment for more chemical agents. Completed development of exposure and analytic methods for selected very low volatile chemical threat agents. Completed studies and published report on human health risk assessment exposure standard for medical applications associated with contact hazards of low volatility CWAs. Expanded previous toxicokinetic and toxicodynamic efforts on a representative spore-forming Biological Warfare Agent (BWA) to include other BWAs, both spore-forming and non spore-			13.922	0.085	1.517

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program			DATE: February 2011		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>		R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>		PROJECT CB2: <i>CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
forming. Assessed the validity of expanding the viral agents model. Investigated human toxicity operational contact hazard assessment, and the effects of alternate toxicological pathways on the overall physiological impacts of high priority NTAs. FY 2011 Plans: Continue research efforts on BWA toxicokinetic and toxicodynamic modeling. All NTA-related efforts re-aligned to Threat Agent Science NTA within this Project. FY 2012 Plans: Expand research efforts on BWA toxicokinetic and toxicodynamic modeling for specific priority viral agents. Investigate potential reservoir hosts for biological agents. Other work will improve understanding of bioavailability following dermal exposures for chemical agents, as well as study in vitro and in vivo binding of agents and analogues. Identification of toxicity of decontamination breakdown products may inform development of decontamination technologies.					
Title: 15) Threat Agent Science Description: Agent Fate: Characterizes fate of chemical and biological material on operationally relevant surfaces; information obtained from the study of particular agents will be used in core programs to support development of detection capabilities, information systems, including hazard prediction tools, and protection and hazard mitigation activities. In FY12, all Agent Fate efforts realigned to Agent Characterization within this budget project (CB2). FY 2010 Accomplishments: Leveraged prior agent fate studies to better bound substrate characteristics, and began to relate agent-substrate interactions for highly variable substrates, such as concrete, sand/soil, and asphalt, and transfer data to predictive models. Characterized effects of substrate composition and structure on persistence and degradation of high priority CWAs and NTAs. Accelerated Agent Fate work on operationally relevant surfaces for highest priority NTAs. Related CWA and NTA adsorption/absorption to chemical properties of both agent and substrate. Characterized vapor and liquid phase transport of high priority CWAs and NTAs through porous and non-porous operationally relevant substrates. Continued studies to determine effects of environmental factors (such as wind, humidity, substrate hydration and temperature) on transport through and off of substrates. Transferred data to predictive models. Refined Droplet Reaction and Evaporation of Agents Model (DREAM), which helps predict evaporation rates of agents from various surfaces, to address variation in program output. Transitioned DREAM modules to defense acquisition programs. Developed NTA hazard models and estimated hazard with extended skin-surface contact. Transitioned data to JEM. FY 2011 Plans: Utilize empirical data to inform prediction of persistence and degradation of select CWAs and BWAs; transition data to JEM. Characterize interaction between biological agents and environmental surfaces, including the impact of ambient conditions (e.g., temperature, relative humidity) and mechanical disturbances.			7.276	0.079	-

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program			DATE: February 2011		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>		R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>		PROJECT CB2: <i>CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
All NTA-related efforts re-aligned to Threat Agent Science NTA within this Project.					
Title: 16) Threat Agent Science Description: Accelerating Agent Sciences: Accelerates CB defense research and development by coupling computational methods and experimental approaches. In FY11, all NTA-related efforts are re-aligned to Threat Agent Science NTA within this Project. FY 2010 Accomplishments: Integrated research in computational techniques with existing computational toxicology, such as, shape signatures, and existing molecular dynamics capabilities to enhance agent fate, physiological response, simulant experiments and predictive modeling. Initiated work providing near term benefits, such as, computational toxicology. Completed CWA Quantum Chemical Modeling (QCM) development and maturation capability baseline for CWA interactions. Applied Quantum Chemical Modeling to develop and accelerate computationally obtained datasets and Quantitative Structure-Activity Relationships (QSAR) derived from the QCM data to highest priority NTA interactions and toxicology.			3.671	-	-
Title: 17) Threat Agent Science Description: Agent Characterization: Examines critical characteristics of chemical and biological warfare agents (CWAs and BWAs, beginning with physiochemical properties and subsequently determining the challenge levels to military personnel in operationally relevant environments that provides key information to development or improvement of both physical and medical countermeasures and decision support tools. Research focuses on: characterizing the realistic threat posed by aerosol and particulate agent dissemination; examining the fundamental mechanisms that contribute to BWAs persistence and transport; understanding the fundamental interactions between agents and substrates; investigating aqueous transport of agents and the underlying mechanisms of binding CB agents onto hydrated surfaces; advancing the understanding of fundamental interactions between agents and substrates; and identifying agent decomposition products harmful to military personnel. In FY12, this area will include research formerly performed under Agent Fate. FY 2010 Accomplishments: Capitalized on previous research to characterize highest priority CWA and NTA chemistry based on structure, physicochemical properties, and molecular interactions. Leveraged prior work to better understand BWA genomic variation as related to preparation methodologies and environmental stresses. Improved sampling methods and agent simulant correlation studies by leveraging established BWA standard characterization and preparation techniques. Transitioned CWA, BWA and NTA simulant selection process and test protocols to support T&E applications and defined the operational envelopes of simulants through the			6.519	0.095	3.025

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program			DATE: February 2011		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>		R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>		PROJECT CB2: <i>CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
<p>acquisition life cycle. Expanded the scope of simulant development to accelerate delivery of characteristics and simulants for highest priority NTAs. Addressed critical characterization work on highest priority NTAs.</p> <p>FY 2011 Plans: Continue BWA research to improve understanding of the relationship of genotype variations on organism virulence, infectivity, and persistence. Sustain efforts to support T&E applications by continued development of CWA and BWA simulants and refine simulant application by expanding agent-simulant correlation studies. All NTA-related efforts re-aligned to Threat Agent Science NTA within this Project.</p> <p>FY 2012 Plans: Expand investigations of fundamental mechanisms that contribute to BWA persistence and transport; transfer information from previous studies to operational models. Identify markers of cultured versus naturally occurring agents, as well as markers of persistence of biological agents. Continue to support test and evaluation needs for both CWA and BWA simulants. Characterize environmental factors affecting persistence and binding to environmental elements such as soil. Advance the understanding of fundamental interactions between agents and substrates in order to improve predictive modeling that supports other capability areas, such as detection and hazard mitigation.</p>					
<p>Title: 18) Threat Agent Science NTA</p> <p>Description: Threat Agent Science NTA: Provides enabling science and technology which informs development and testing of NTA defense technology such as detection, decontamination, protection, hazard assessment, and more. This preliminary assessment provides the basis for all countermeasure development and assessment.</p> <p>FY 2011 Plans: Establish human NTA operational toxicity estimates and interim human health risk assessments. Characterize the effects of alternate toxicological pathways. Expand agent fate studies to additional agent-substrate interactions. Correlate agent adsorption/absorption coefficients to chemical properties. Expand research on NTA liquid and solid phase transport to include re-suspension of particulates. Apply computational tools to identify data requirements and accelerate QSAR application to NTA interactions with operational substrates and toxicology issues. Correlate human effects to contact with operationally-relevant surfaces. Further research on NTA chemistry. Continue development of NTA simulants and simulant correlation studies.</p> <p>FY 2012 Plans: Continue efforts from previous year, working through the list of priority agents. Provide necessary operational and residual contact hazards as well as aerosol and percutaneous toxicity standards for NTAs. Deliver prioritized fundamental analysis,</p>			-	17.200	25.497

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program		DATE: February 2011	
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>	R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	PROJECT CB2: <i>CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2010	FY 2011
including physicochemical properties such as volatility, solubility, mass transport, reactivity, stability and other factors. Examine physical parameters that govern NTA stability on operational materials.			
Title: 19) Information Systems Technology Description: Warning and Reporting Information & Analysis: Emphasis on developing science and technologies for collaborative information management, fusion of disparate information from multiple sources, environmental databases and modeling, fusion of syndromic/diseases surveillance data, and synthetic environments for model performance evaluation and acquisition decisions. FY 2010 Accomplishments: Utilized newly released field test data to conduct validation and verification (V&V) of outdoor Source Term Estimation (STE) algorithms. Initiated development of a networked chemical and biological (CB) detector false alarm reduction capability for an advanced development program (Joint Warning and Reporting Network (JWARN)). Initiated development of rapid STE tool for JWARN. Expanded virtual test environment model to include fielded sensors and enhanced geospatial information. Expanded and improved data assimilation techniques for linking chemical, environmental and medical surveillance sensor data with computer based applications. Continued development of advanced STE, Hazard Refinement (HR) and Sensor Placement Tool (SPT) algorithms for use in complex environments (e.g., variable terrain, urban, water). Extended coupling between environmental parameters and advanced development programs. Continued development of a tool that continuously refines and updates the contamination footprint through rapid assimilation of limited and disparate information into meteorological, transport and dispersion, and virtual environment models. FY 2011 Plans: Refine advanced STE and HR algorithms for use in complex environments (e.g., variable terrain, urban, water), based on results of field trial-based V&V effort. Complete testing and V&V of first-generation networked CB detector false alarm reduction capability for an advanced development program (JWARN). Expand and improve data assimilation techniques for linking chemical, environmental, medical surveillance, and other disparate sensor data with computer based applications. Complete development of STE, HR, and SPT for use in complex environments. Continue to enhance coupling between environmental parameters and advanced development programs. Finalize development of a tool that continuously refines and updates the contamination footprint through rapid assimilation of limited and disparate information into meteorological, transport and dispersion, and virtual environment models. FY 2012 Plans: Initiate study on integration of biosurveillance data with disease spread models to enable early warning and reporting capabilities. Investigation will include approaches and tools to automatically access, process and store biosurveillance data, architecture to search stored raw and processed biosurveillance data including adapting existing taxonomies or ontologies to facilitate		6.608	3.844
			5.764

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program			DATE: February 2011		
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 2: Applied Research		R-1 ITEM NOMENCLATURE PE 0602384BP: CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	PROJECT CB2: CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)		
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
interoperability, and approaches to facilitate using the architecture in near real time to update disease spread models with new biosurveillance data. Complete advanced STE and HR algorithms for use in complex environments (e.g., variable terrain, urban, water), based on results of field trial-based V&V effort. Continue to expand and improve data assimilation techniques for linking chemical, environmental, medical surveillance, and other disparate sensor data with computer based applications. Complete enhancing coupling between environmental parameters and advanced development programs.					
Title: 20) Information Systems Technology Description: Hazard Prediction and Information Analysis: Improve battlespace awareness by accurately predicting hazardous material releases, atmospheric transport and dispersion, and resulting human effects. Develop predictive capability for the source term of releases of CB agents or industrial materials from CB or accidents. FY 2010 Accomplishments: Initiated development of a high altitude post-missile intercept hazard prediction model for integration with Joint Effects Model (JEM). Continued optimization of methods to significantly improve performance of transport and dispersion hazard models for JEM in both open air and urban environments which used Second Order Closure Puff Atmospheric Transport and Dispersion (SCIPUFF AT&D) and Micro-Stationary Wind Fit with Turbulence (Micro-SWIFT). Initiated development of a waterborne transport model by beginning investigation of the transport methods of chemical agents. Continued advancing modeling techniques for chemical, biological, and industrial source models IFAC, ITRANS, and CBFAC. Continued experimental verification of models by way of small scale tests initiated in FY09. FY 2011 Plans: Continue to develop a high altitude post-missile intercept hazard prediction model for chemical, biological, and nuclear dispersion and integrate with advanced development programs. Continue to develop models for waterborne transport and dispersion of chemical agents. Continue to improve and optimize transport and dispersion models in open and urban environments. Implement source backtracking in advanced urban models. Implement methods for foreign regions as well as dynamic climatology. FY 2012 Plans: Continue development of a waterborne transport tool by beginning investigation of transport methods for biological agents and other materials as well as beginning a feasibility study of waterborne inverse species transport module. Further develop a high altitude post-missile intercept hazard prediction model for eventual integration into the JEM supplemented by small scale testing for model validation. Initiate enhancement of urban dispersion models to include source characterization/backtracking for eventual integration into the JEM. Initiate implementation and testing of new numerical schemes for future establishment of 64-bit/multi-core capable models.			5.529	3.030	3.113
Title: 21) Information Systems Technology			-	-	4.547

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program			DATE: February 2011		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>		R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>		PROJECT CB2: <i>CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
<p>Description: Operations Planning & Information Analysis: Develop decision support tools and information management capabilities for planning and real-time analysis to determine and assess operational effects, risks, and impacts of CBRN incidents on decision making. Focus areas include consequence management, population modeling, and human knowledge management.</p> <p>FY 2012 Plans: Continue development of efforts previously funded under Simulation Analysis and Planning in FY11 also under this project. Initiate studies on regional social/cultural norms for application in agent based models. Initiate regional study of social reaction to disease and disease mitigation strategies to support biosurveillance. Initiate development of human cognitive models that incorporate the effects of chemical biological agent interaction with other battle stressors to facilitate operational decision making.</p>					
<p>Title: 22) Information Systems Technology</p> <p>Description: Systems Performance Information & Analysis: Develop Chemical, Biological, Radiological and Nuclear (CBRN) data sharing capabilities and simulation tools.</p> <p>FY 2010 Accomplishments: Developed data collection and exchange methodologies for implementation in the Chemical, Biological, Radiological and Nuclear (CBRN) Data Backbone. Designed CB Warfare Effects Manual.</p> <p>FY 2011 Plans: Construct a plan for development of an authoritative source (the CB Agent Effects Manual or CB-1; previously, the CB Warfare Effects Manual) capturing analytical methods for evaluating the effects of chemical and biological warfare on equipment, personnel, and operations. Develop capabilities to simulate decontamination processes to enhance the CBDP's ability to evaluate decontaminants and decontamination systems. Continue to explore the technical feasibility and potential utility of a bio-surveillance data analysis platform.</p> <p>FY 2012 Plans: Initiate development of an authoritative manual capturing analytical methods for evaluating the effects of chemical and biological warfare on equipment, personnel, and operations.</p>			3.660	3.502	0.569
<p>Title: 23) Information Systems Technology</p> <p>Description: Medical & Surveillance Information & Analysis: Integrate existing disparate military and civilian datasets into advanced warning systems, and leverage and enhance epidemiological models and algorithms for disease prediction, impact and biological threat assessment. Contribute to the development of global, near real time, disease monitoring and surveillance systems that address secondary infection, fuse medical syndromic, environmental, and clinical data, and feed into agent-based</p>			-	-	6.059

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program			DATE: February 2011		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>		R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>		PROJECT CB2: <i>CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
epidemiological modeling, medical resource estimation and decision support tools. Focus areas include health/human effects modeling including casualty estimation, agent-based epidemiological modeling and fusion of disease surveillance data. FY 2012 Plans: Continue development previously funded under Simulation Analysis and Planning in FY11 also in this project. Continue effort on biosurveillance data stream evaluation and analysis. Initiate effort to devise structured expansion roadmap for agent-based epidemiological models for Outside Contiguous United States (OCONUS) and special population analysis to model emerging disease and the effects of targeted countermeasures.					
Title: 24) Information Systems Technology Description: Simulation Analysis and Planning: Develop decision support tools and information management capabilities for planning and real-time analysis to determine and assess operational effects, risks, and impacts of CBRN incidents on decision making. Focus areas include consequence management, human knowledge management, health/human effects modeling including casualty estimation, and fusion of diseases surveillance data. FY 2010 Accomplishments: Developed and improved methodologies to apply CB operational effects in tactical, operational and strategic level models for mobile forces, shipboard modeling, fixed sites and tactical aircraft. Continued development of Incident Management/Consequence Management (IM/CM) tools and capabilities. Continued refinement and expansion of decision support tools for advanced development efforts. Completed distributed modeling research. Refined and updated secondary infection models and NBC Casualty Resource Estimation Support Tool (NBC CREST) human effects models to reflect revision of NATO's Allied Medical Publication 8 (AMedP-8). Initiated development of casualty estimation methodology for CBRN agents including Non-Traditional Agents. Initiated development of medical resource estimation and medical countermeasure models for enhanced situational awareness and course of action analysis. Initiated development of epidemic characterization and prediction capability for crisis response planning. FY 2011 Plans: Complete development of refined versions of secondary infection models and human effects models to reflect revision of NATO's AMedP-8. Initiate development of additional casualty estimation modules for agents not in NATO's AMedP-8, including Non-Traditional Agents. Continue development of contagious/infectious disease models. Continue developing efforts aimed at integrating CB operational effects in tactical and operational level models for mobile forces, shipboard modeling, fixed sites and tactical aircraft. Further develop IM/CM tools and capabilities. Initiate development of capabilities that leverage and integrate			8.048	7.395	-

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program			DATE: February 2011		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>		R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>		PROJECT CB2: <i>CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
existing early detection and disease surveillance data for inclusion into advanced development efforts. Develop route planning and evacuation/shelter-in-place decision aids.					
Title: 25) Information Systems Technology NTA Description: Modeling & Simulation for Non-Traditional Agents (NTA): Provide modeling of NTA materials for hazard prediction. Develop NTA source term algorithms for intentionally functioning weapons, counter-proliferation scenarios (bomb on target), and missile intercept. "Intentionally Functioning Weapons" refers to the case where a missile has released its chemical or biological payload as it was designed, rather than where the release was caused by our missile interdiction. Investigate NTA agent fate for secondary effects, environmental/atmospheric chemistry, atmospheric and waterborne transport and dispersion, human effects, model V&V, scaled testing, casualty estimation, and supporting data management FY 2012 Plans: Establish initial methodologies of defining NTA source terms for relevant scenarios. Begin establishment of a classified database for linking NTA types to weapon system types. Expand material file collection to include those NTAs on which there is sufficient initial data. Create initial priority list of remaining agents with data gaps. Initiate the establishment of capabilities for data collection on NTA data gaps. Initiate planning and implementation of small scale testing for NTA simulants for use in creating and verifying NTA modeling source terms.			-	-	1.442
Title: 26) Detection Description: Chemical and Biological Point Detection Technology: Emphasis on the detection and identification of chemical and biological threats. Objectives include the development of nanoscale detector for sensing of chemical and biological agents, design for prototype whole pathogen genome sequencing system, and development of a portable point detector for chemical warfare (CW) detection in potable water. FY 2010 Accomplishments: Continued concept development of nano-scale biological agent identification and sensing technologies. Continued development of technology to completely sequence entire pathogen genomes with automated sample preparation. Continued feasibility studies of nanoscale detection systems. Completed transition of MEMS technology from DARPA and integrated it into a MEMS FTIR sensor system as next generation chemical warfare agent detector. Continued studies to increase understanding of critical biological antigen variability. Continued a scientific analysis on the technical impacts of the presence of agents on surfaces and expand to include aerosol and operational scenarios due to the presence of NTAs. Continued assessment of chemical fate of			10.194	5.289	8.923

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program			DATE: February 2011		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>		R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>		PROJECT CB2: <i>CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
chemicals in potable water. Continued feasibility development of plant sentinel concept. Initiated development of MEMS version of a gas chromatograph-mass spectrometer (GC-Mass Spec) technology in collaboration with DARPA. FY 2011 Plans: Continue concept development of nano-scale biological agent identification and sensing technologies. Continue feasibility studies of nanoscale detection systems. Demonstrate MEMS FTIR sensor system. Demonstrate technology to completely sequence entire pathogen genomes with automated sample preparation. Complete studies to increase understanding of critical biological antigen variability. All NTA-related efforts re-aligned to Detection NTA within this Budget Activity. FY 2012 Plans: Continue concept development of nano-scale biological agent identification and sensing technologies. Continue feasibility studies of nanoscale detection systems. Continue integration studies for the NGCPD based on MEMS components for GC, IR, and MS. Continue development of breadboard prototype for complete sequencing entire pathogen genomes with automated sample preparation which also applies to biosurveillance.					
Title: 27) Detection Description: Chemical and Biological Stand-off Detection Technology: Emphasis on the detection and identification of chemical and biological threats to include NTAs in near real time at a distance from the detector. Future programs focus on the improvement of algorithms, excitation sources, and detector elements to increase range, reduce false positives, increase sensitivity, and reduce cost. FY 2010 Accomplishments: Continued algorithm development to increase range capabilities and reduce false positives. Continued first generation active infrared standoff biological classification capabilities development. Continued design of first generation chemical standoff detection and identification capabilities. Completed models of technology to meet the needs to detect contamination on surfaces in a post decontamination application. Continued to evaluate and assess technology for scattering optical techniques, non-scattering optical standoff techniques, and off-gassing techniques for down-selection of breadboard design. FY 2011 Plans: Complete algorithm development to increase range capabilities and reduce false positives. Complete work on first generation active infrared (IR) standoff biological classification capabilities. Complete evaluation and assessment of technology for scattering optical techniques, non-scattering optical standoff techniques, and off-gassing for down-selection of breadboard design. All NTA-related efforts re-aligned to Detection NTA within this Project.			14.366	9.100	-
Title: 28) Detection NTA			-	12.000	13.066

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program									DATE: February 2011		
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 2: Applied Research			R-1 ITEM NOMENCLATURE PE 0602384BP: CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)				PROJECT CB2: CHEMICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)				
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2010	FY 2011	FY 2012
Description: Primary focus is to assess the potential of optical technologies to meet the needs to detect the presence of NTAs. FY 2011 Plans: Complete a scientific analysis on the technical impacts of the presence of agents on surfaces due to the presence of NTAs. Complete assessment of chemical fate of chemicals in potable water. Continue feasibility development of plant sentinel concept. Initiate development from technology concepts and models to meet the needs to detect contamination on surfaces in pre and post decontamination application. Initiate concept designs for chemical aerosols point detection system. FY 2012 Plans: Continue feasibility development of plant sentinel concept. Continue development from technology concepts and models to meet the needs to detect contamination on surfaces in pre and post decontamination application. Complete designs for chemical aerosols point detection system. Initiate integration studies for chemical aerosol detection into the NGCPD.											
Accomplishments/Planned Programs Subtotals									110.937	88.897	97.774
C. Other Program Funding Summary (\$ in Millions)											
Line Item	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost
• CB1: CHEMICAL/BIOLOGICAL DEFENSE (BASIC RESEARCH)	33.630	31.041	0.000		0.000	0.000	0.000	0.000	0.000	0.000	64.671
• CB3: CHEMICAL BIOLOGICAL DEFENSE (ATD)	26.964	15.410	23.818		23.818	30.514	37.806	38.139	38.586	Continuing	Continuing
• TE3: TEST & EVALUATION (ATD)	12.296	11.875	11.199		11.199	11.081	0.992	0.991	0.990	Continuing	Continuing
• TT3: TECHBASE TECHNOLOGY TRANSITION	7.381	4.504	0.000		0.000	0.000	0.000	0.000	0.000	0.000	11.885
D. Acquisition Strategy N/A											
E. Performance Metrics N/A											

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program **DATE:** February 2011

APPROPRIATION/BUDGET ACTIVITY				R-1 ITEM NOMENCLATURE				PROJECT			
0400: Research, Development, Test & Evaluation, Defense-Wide BA 2: Applied Research				PE 0602384BP: CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)				CI2: CONGRESSIONAL INTEREST ITEMS (APPLIED RESEARCH)			
COST (\$ in Millions)	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost
CI2: CONGRESSIONAL INTEREST ITEMS (APPLIED RESEARCH)	27.186	-	-	-	-	-	-	-	-	0.000	27.186

A. Mission Description and Budget Item Justification

The efforts in this project include congressional interest programs for FY10.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2010	FY 2011
Congressional Add: Chem/Bio IR Detection System	1.892	-
FY 2010 Accomplishments: Developed an advanced chemical and biological detection system using a common platform to include detection of emerging novel agents and toxic industrial chemicals. Designed and built a prototype and automated detector system for trace level detection of chemical and biological warfare (CW and BW) agents in water and air using a common detection platform.		
Congressional Add: HyperAcute Vaccine Development	3.585	-
FY 2010 Accomplishments: Determined how the alpha-galactosidase adjuvant technology can improve the efficacy of new and existing vaccines, which should lead to a reduction in the overall number of required vaccinations and a decrease of the vaccine dose, thus making vaccine production more cost-effective and, for the end user (i.e., government: Strategic National Stockpile) more affordable.		
Congressional Add: Chemical Agent Fate Appropriate Response Tool	1.593	-
FY 2010 Accomplishments: Developed a model/tool that affords the user the probabilities and risks associated with a chemical contamination event and recommends the most appropriate response to mitigate the hazard.		
Congressional Add: Botulinum Neurotoxin Research	1.992	-
FY 2010 Accomplishments: Developed an assay which is designed to detect Botulinum (A-G) in the environment and on exposed animals, humans and culture cells. The objective is to design a simplified hand-held fluorescence detection system for this type of assay.		
Congressional Add: Miniaturized Chemical Detector for Chemical Warfare Protection (ChemPen)	1.593	-

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program		DATE: February 2011
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>	R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	PROJECT CI2: <i>CONGRESSIONAL INTEREST ITEMS (APPLIED RESEARCH)</i>
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2010	FY 2011
FY 2010 Accomplishments: Developed a functional interferometer, integrated it into a brassboard spectrometer system, and demonstrated spectral acquisition which could be used to detect chemicals, such as sulfur-hexafluoride (SF6).		
Congressional Add: Chemical and Biological Resistant Clothing FY 2010 Accomplishments: Developed a material capable of simultaneously being lightweight, robust, breathable, and resistant to chemical and biological agents. The objective of this effort is identification and lab-scale production of a semi-permeable membrane polymer that is lightweight, breathable, and mechanically robust for use as a barrier layer within a multi-layer protection ensemble garment worn by military personnel/first-responders.	1.593	-
Congressional Add: Botulinum Toxin Treatment Therapy FY 2010 Accomplishments: Developed new therapies for botulinum toxin poisoning to protect the civilian population against other bioterrorism threats.	0.797	-
Congressional Add: PaintShield for Protecting People from Microbial Threats FY 2010 Accomplishments: Developed the PaintShield coating technology, a cost-effective, interior paint platform that will render microbiological threats harmless upon contact, to facilitate significant increases in research and development programs for an expanded array of related environmental health applications.	1.992	-
Congressional Add: Mismatch Repair Derived Antibody Medicines to Treat Staphylococcus-derived Bioweapons FY 2010 Accomplishments: Developed a highly efficient therapeutics to treat exposure to potential biological weapons. These efforts have resulted in the development of potent lead antibodies, one of which can neutralize staphylococcus enterotoxin B (SEB). Conducted final studies using Good Laboratory Practices (GLP)-grade materials in GLP non-human primate studies as a final validation step before advancing the program into human clinical trials.	0.996	-
Congressional Add: Advanced Development of Antiviral Prophylaxis and Therapeutics FY 2010 Accomplishments: Continued the research on an anti-hemorrhagic fever virus (HFV) drug discovery and lead optimization efforts. Continued advancement of at least two chemical series through the first critical steps toward filing an Investigational New Drug (IND) application: efficacy, safety and mechanism of action.	2.987	-
Congressional Add: Potent Human Monoclonal Antibodies Against BoNT, A, B and E (Botulinum Neurotoxins) Suited for Mass Production and Treatment of Large Populations	0.996	-

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program									DATE: February 2011		
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 2: Applied Research				R-1 ITEM NOMENCLATURE PE 0602384BP: CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)				PROJECT CI2: CONGRESSIONAL INTEREST ITEMS (APPLIED RESEARCH)			
B. Accomplishments/Planned Programs (\$ in Millions)							FY 2010	FY 2011			
FY 2010 Accomplishments: Developed humanized monoclonal antibodies for passive immunization of military or civilian individuals capable of neutralizing botulinum toxins BoNT/A, BoNT/B, and BoNT/E.											
Congressional Add: Countermeasures to Chemical and Biological Controls-Rapid Response							2.788	-			
FY 2010 Accomplishments: Developed new, low cost, detection technologies with a high level of differentiation that can be deployed independently or integrated into existing and future CBRN reconnaissance systems.											
Congressional Add: MEMS Sensors for Real-time Sensing of Weaponized Pathogens							1.992	-			
FY 2010 Accomplishments: Developed wearable, diamond-based MEMS biosensors for first responders or Warfighters that detect weaponized pathogens in real-time.											
Congressional Add: Mobile Rapid Response Prototype							2.390	-			
FY 2010 Accomplishments: Developed prototype capability to incorporate commercial "best in class" components, processes, tools, techniques, and training to ensure that responders will be able to provide appropriate treatment, diagnose disease with forward-deployable assays, and ultimately minimize the toll on human life.											
Congressional Adds Subtotals							27.186	-			
C. Other Program Funding Summary (\$ in Millions)											
Line Item	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cos
• CI1: CONGRESSIONAL INTEREST ITEMS (BASIC RESEARCH)	7.968	0.000	0.000		0.000	0.000	0.000	0.000	0.000	0.000	7.968
• CI3: CONGRESSIONAL INTEREST ITEMS (ATD)	30.172	0.000	0.000		0.000	0.000	0.000	0.000	0.000	0.000	30.172
D. Acquisition Strategy											
N/A											
E. Performance Metrics											
N/A											

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program **DATE:** February 2011

APPROPRIATION/BUDGET ACTIVITY				R-1 ITEM NOMENCLATURE				PROJECT			
0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>				PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>				TB2: <i>MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>			
COST (\$ in Millions)	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost
TB2: <i>MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	54.858	43.858	84.747	-	84.747	85.493	76.011	52.527	75.583	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project (TB2) funds applied research on vaccines, therapeutic drugs, and diagnostic capabilities to provide effective medical defense against validated biological threat agents or emerging infectious disease threats including bacteria, toxins, and viruses. Innovative biotechnology approaches will be incorporated to advance medical systems designed to rapidly identify, diagnose, prevent, and treat disease due to exposure to biological threat agents. Categories for this project include core science efforts in biological defense capability areas, such as Pretreatments, Diagnostics, and Therapeutics. Medical Science and Technology (S&T) efforts in this Budget Activity refine promising medical initiatives identified in Budget Activity 1, resulting in the development of countermeasures to protect against and treat the effects of exposure to chemical, biological, and radiological (CBR) agents.

This project also includes efforts such as the Transformational Medical Technologies Initiative (TMTI). Effective FY12 this effort is funded as the Transformational Medical Technologies (TMT) Program. The program was launched to respond to the threat of emerging or intentionally engineered biological threats. TMT's mission is to protect the Warfighter from genetically engineered biological threats by providing a rapid response capability from identification of pathogens to the delivery of medical countermeasures. This mission is accomplished through two main efforts: 1) developing broad spectrum (multi-agent) therapeutics against biological agents (e.g. one drug that treats multiple agents); and 2) developing platform technologies to assist in the rapid development of medical countermeasures (MCMs) in response to biological agents (e.g. developing new and innovative ways to mass produce drugs in the event of a biological incident).

The Medical Countermeasures Initiative (MCMI) was established to coordinate inter-related advanced development and flexible manufacturing capabilities, based on public-private partnership agreements between the government and industry, providing a dedicated, cost-effective, reliable, and sustainable MCM process that meets the warfighter and national security needs. Specifically, the MCMI will provide the capability for the advanced development and flexible manufacturing of biological MCM (to include TMT developed MCMs) to address CBRN threats, including novel and previously unrecognized, naturally-occurring emerging infectious diseases. MCMI efforts within S&T are concentrated in three areas: 1) novel platform/expression systems for MCMs, 2) advancement of regulatory science, and 3) advancements in flexible manufacturing technologies for MCMs.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2010	FY 2011	FY 2012
Title: 1) Diagnostics (Biosurveillance)	7.518	6.994	13.933
Description: Diagnostic Technologies: Development and verification of rapid, sensitive, and specific tests for the identification of Biological Warfare Agents (BWAs) and their expressed toxins in biological fluids of Warfighters for the diagnosis of exposure/infection. Discovery of biomarkers of response to exposure. Evaluation of next generation diagnostic technologies including portable instrument platforms, highly parallel and informative testing formats, and nanotechnology applications.			
FY 2010 Accomplishments:			

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program			DATE: February 2011		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>		R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>		PROJECT TB2: <i>MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
<p>Implemented restructured intra- and inter-agency strategy for Next Generation Diagnostic System (NGDS) candidate technology assessment and maturation. Continued development of panel of potential pre-symptomatic indicators of exposure/infection. Developed affinity reagent production and characterization pipeline and apply materials and data coordination with technology maturation efforts. Developed affinity-based amplification prototype assays for application on PCR-based fluorometric system. Applied nano-diagnostic technology to demonstrate BWA viability and analytic application. Developed target enrichment methods for rapid diagnostic de novo sequencing of BWA directly from clinical matrices. Developed micro-RNA library and study diagnostic utility.</p> <p>FY 2011 Plans: Develop high-throughput technologies for identification, evaluation, and validation of agent-specific genetic and immunological assay targets using sequencers and microarrays. Complete development and assess performance of affinity-based protein expression amplification methods. Continue to discover and develop pre-symptomatic diagnostic signatures for additional agents and investigate diagnostic utility as early indicators of exposure/infection in animal models. Evaluate nano diagnostic technologies for ease-of-use, sensitivity, specificity and cost. Continue development and application of rapid sequencing technology and target enrichment for deployable field environment. Investigate advancement of technologies and procedures for broad multiplex detection of agent gene expression, proteomic and antibiotic resistance profiles. Develop a geographically representative strain collection and assay(s) capable of detecting an emerging threat agent of high genetic variability.</p> <p>FY 2012 Plans: Verify performance of informative genetic and affinity probes and optimize number of probes required to capture predictive signature coverage. Verify performance of pre-symptomatic diagnostic biomarker panels in blinded BWA and emerging threat pathogen-exposed animal samples. Develop pan-emerging threat agent genotyping assay for fieldable sequence-based genetic analyzer to supplement/replace strain-specific assays.</p>					
<p>Title: 2) Medical Countermeasures Initiative (MCMI)</p> <p>FY 2012 Plans: Conduct studies to explore increasing the efficiency, responsiveness and speed of biopharmaceutical manufacturing through use of more flexible, non-traditional host-vector systems. Initiate and refine development of multi-product/multi-use platform technologies for flexible manufacturing processes for MCMs. Evaluate and exploit the regulatory advantages of such systems, with the intent that approval of the platform for one product will simplify subsequent approvals of other products based on the same system.</p>			-	-	6.663
<p>Title: 3) Pretreatments</p>			4.050	5.254	5.051

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
<p>Description: Bacterial/Toxins Vaccines: Generate novel or improved vaccines against bacterial and toxin biothreat agents, and demonstrate preliminary efficacy in small animal models. Identify correlates of protective immunity in animals models.</p> <p>FY 2010 Accomplishments: Tested the efficacy of Burkholderia vaccine candidates against aerosol challenge in small animal models. Initiated study to determine the therapeutic regimen needed in conjunction with a vaccine to eliminate residual Burkholderia organisms and began evaluation of the immune response elicited by the vaccine. Used comparative animal studies to test the efficacy of disease inactivated, but metabolically active vaccine candidates against Brucella species. Initiated study to compare the ability of the disease inactivated, but metabolically active vaccine candidates to protect mice against aerosol challenge with distinct strains of Brucella following oral immunization. Continued to test the immune stimulation and effectiveness of novel anthrax vaccines (e.g., multi-component genetically altered vaccines composed of spore antigens, etc.) to combat emerging and genetically engineered strains. Initiated studies aimed at generating a second-generation vaccine that protects against aerosolized Type A Francisella tularensis.</p> <p>FY 2011 Plans: Continue aerosol efficacy studies in mice for Brucella and Burkholderia vaccine candidates. Work to improve the efficacy of the most promising vaccine candidates against Burkholderia and Brucella by initiating studies that vary the route of immunization, dose and vaccination schedule. Begin investigating whether the efficacy of the Brucella and Burkholderia vaccine candidates can be approved by co-administering the vaccines with nonspecific stimulators of the immune response (i.e., adjuvants). Test the ability of antibiotics to remove residual Burkholderia from vaccinated animals to prevent reactivation of disease. Identify measures of immunity elicited by vaccine candidates against Brucella and Burkholderia. Test the efficacy of novel next-generation, multi-valent anthrax vaccines in small animal models against aerosol challenge. Determine the immune stimulation capability of novel subunit vaccines comprised of proteins involved in a common virulence pathway shared by most gram negative bacteria, including Yersinia pestis. Investigate the potential of outer membrane proteins isolated from Type A Francisella tularensis to serve as vaccine candidates against aerosol challenge with the pathogen in small animal models.</p> <p>FY 2012 Plans: Improve upon the most promising existing whole-cell vaccine candidates directed against Burkholderia and Brucella species. Identify correlates of immunity, elicited by Brucella and Burkholderia species vaccine candidates, which predict vaccine efficacy. Continue efforts designed to examine the efficacy of adjuvants co-administered with existing vaccine candidates against Burkholderia and Brucella species. In a concurrent effort, open investigative avenues in search of next-generation vaccine candidates directed against Burkholderia and Brucella species. Continue efforts to boost immune response to the currently licensed anthrax vaccine using novel adjuvants which might have applicability to other vaccine candidates in the future. Additionally, research will continue to produce vaccine candidates designed to protect against emerging or genetically engineered</p>					

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APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>		R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>		PROJECT TB2: <i>MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
anthrax strains. Examine the efficacy of rationally designed, next-generation Type A Francisella tularensis vaccine against aerosol challenge in rat and non-human primate models. Maintain research designed evaluate outer membrane proteins isolated from Type A Francisella tularensis as vaccine candidates against aerosol challenge with the pathogen in small animal models.					
Title: 4) Pretreatments Description: Viral Vaccines: Design vaccines against the Filoviruses (Ebola and Marburg strains) and Alphaviruses (VEE, EEE, WEE) using distinct vaccine platforms, and demonstrate preliminary efficacy in animal models. Identify correlates of protective immunity in animal models. FY 2010 Accomplishments: Identified correlates of immunity for alphavirus (VEE, EEE, WEE) vaccine candidates. Defined immune correlates of protection for mature Marburg and Ebola virus vaccine candidates. Developed vaccine candidates for emerging filovirus strains (e.g. Ebola Uganda strain). FY 2011 Plans: Further define immune correlates of protection for alphavirus (i.e., EEE and WEE) vaccine candidates. Continue to characterize the immune response to Ebola and Marburg viruses in order to identify correlates of protection in animal models, and establish assays to measure these immune correlates. Assess the immune stimulation and effectiveness of vaccine candidates against a new strain of the Ebola virus, Ebola Bundibugyo, in animal challenge models. FY 2012 Plans: Continue to characterize the innate, humoral and cellular immune response of the Ebola/Marburg vaccine candidates in the relevant animal models. Produce, characterize, optimize and test reagents for Filovirus immunological assays. Develop assays to measure innate, cellular, and humoral immune responses to Alphaviruses (i.e., EEE, WEE and VEE) which predict protective immunity. Produce, characterize, optimize and test reagents for Alphavirus immunological assays.			2.948	0.525	0.484
Title: 5) Pretreatments Description: Vaccine Platforms and Research Tools: Design novel multi-agent vaccine platforms capable of expressing multiple antigens, investigate the ability of non-specific stimulators of immunity to enhance the effectiveness of newly generated vaccines, characterize alternative vaccine delivery (needle-free) methods and novel vaccine stabilization methodologies, and conduct studies to further advance a laboratory based, human artificial immune system to render it capable of predicting the human immune response to biodefense vaccines under development. FY 2010 Accomplishments:			4.229	4.729	4.567

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
<p>Researched multiagent vaccines, immune interference, immune stimulation formulations, vaccine delivery/stabilization, and efforts to predict the human immune response to vaccine candidates. Developed and tested new platform technologies that support the expression of multiple antigens. Explored new multi-agent vaccine formulations for immune stimulation in animal models. Further examined devices for efficient administration of DNA vaccines. Began evaluating alternate, needle-free immunization strategies (i.e., intranasal, oral, and transdermal administration) with current vaccine candidates (non-DNA) against biological threats. Conducted studies to advance the laboratory based artificial human immune system to optimize antibody production. Obtained samples from individuals in the Former Soviet Union that had either been vaccinated against or infected with endemic pathogens considered to be threat organisms in order to evaluate the human immunologic response to these agents and/or vaccines. Evaluated new immune stimulating formulations for their ability to enhance vaccine effectiveness in animal models by examining the antibody and cell-based immune responses.</p> <p>FY 2011 Plans: Continue to construct new multi-agent vaccine formulations utilizing platform technologies that support the expression of multiple antigens, and test these multi-agent vaccines for immune stimulation in small animal models. Compare an intra-dermal versus intra-muscular electric field device for delivery of DNA vaccines against bio-threat agents in small animals. Continue studies to advance the laboratory based, surrogate human immune system termed the Modular Immune In vitro Construct (MIMIC), which provides a three-dimensional peripheral tissue model intended to reliably reproduce the human immune response. Complete optimization of the production of high affinity antibodies by the MIMIC in response to biodefense vaccines, and develop a sensitive fluorescent-based assay to assess the functionality of the antibodies generated. Adapt the MIMIC to function as an infectious disease model for alphaviruses and filoviruses. Use these MIMIC in infectious disease models to begin to define human correlates of protective immunity against alphaviruses and filoviruses. Initiate studies to develop methodologies that render different types of vaccine platforms (i.e., viral vector, inactivated virus, virus like particles, and attenuated bacteria, etc.) stable in variable and extreme temperatures.</p> <p>FY 2012 Plans: Continue to develop new platform technologies that support the presentation of multiple antigens to the immune system. Develop relevant animal models for the evaluation of the immune response to multi-antigen platforms. Continue studies to develop alternative methodologies for vaccine delivery (i.e., electroporation) via intra-muscular or intra-dermal administration. Continue studies to advance the surrogate human immune system, MIMIC (i.e., Modular Immune In vitro Construct), which provides an in vitro assessment of the human immune response. Complete studies to assess the cross-reactivity of antigens present in different Filoviruses and Alphaviruses. Use MIMIC to define human correlates of immunity in responses various bio-threat agents. Continue studies to develop methodologies which remove the need for cold storage and transport for vaccines and renders them stable in variable and extreme temperatures.</p>					
Title: 6) Therapeutics			4.729	1.600	5.792

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
<p>Description: Viral Therapeutics: Identify, optimize and evaluate lead candidate therapeutics for efficacy against viral pathogens.</p> <p>FY 2010 Accomplishments: Initiated drug discovery for a second novel orthopox drug with a mechanism distinct from ST-246, a low-molecular-weight compound that is active against multiple orthopoxviruses. Expanded drug discovery efforts for alphaviruses (VEE, EEE, and WEE). Established clinical protocols to obtain human clinical samples from filovirus outbreaks in the Democratic Republic of the Congo. Tested and evaluated lead candidate therapeutic compounds in relevant animal challenge models. Continued testing of heavy metal nanoparticle-based therapeutics for the ability to prevent viral infection in animal models. Identified lead compounds from small molecule library screening and optimize their action through medicinal chemistry. Tested and evaluated small protein fragments to determine if their ability to prevent a virus from binding to cells represents a viable therapeutic interdiction point for designated viral pathogens.</p> <p>FY 2011 Plans: Identify FDA approved drug combinations with efficacy against alphavirus infection. Identify and develop small molecule inhibitors to specific host factors required for alphavirus pathogenesis. Conduct structure-based screening of chemical libraries to identify inhibitors of alphavirus proteins. Utilize medicinal chemistry to optimize antiviral activity of lead compounds. Identify therapeutic inhibitors of orthopoxvirus infection by targeting required host and viral tyrosine phosphatases.</p> <p>FY 2012 Plans: Validate FDA approved drug combinations against alphavirus infection. Continue optimization of pathogen and host directed small molecule inhibitors for alphaviruses. Identify and evaluate novel broad-spectrum host and pathogen directed small molecule therapeutics for emerging infectious diseases (i.e. alphavirus, filovirus, flavivirus, arenavirus, bunyavirus). Optimize therapeutic inhibitors of host and viral tyrosine phosphatases for orthopoxvirus infection.</p>					
<p>Title: 7) Therapeutics</p> <p>Description: Bacterial Therapeutics: Identify, optimize and evaluate lead therapeutic candidates effective against designated bacterial threat agents.</p> <p>FY 2010 Accomplishments: Completed evaluation of bacterial phosphatase inhibitors in a mouse model of plague infection. Tested and evaluated lead candidate small molecules to determine their antimicrobial activity. Screened commercially available antimicrobial in advanced clinical development for their activity in the laboratory against bacterial threat agents.</p> <p>FY 2011 Plans:</p>			2.684	4.100	5.932

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
Continue the identification of commercially available antimicrobials in advanced clinical development with laboratory assayed activity against bacterial threat agents. Assess compounds identified in high content imaging assays for their antimicrobial activity in relevant animal challenge models. FY 2012 Plans: Expand FDA approved drug screening program for Burkholderia, Francisella tularensis and determine in vitro susceptibilities. Continue evaluation of novel compounds against bacterial biological warfare agents. Optimize lead series of MurB compounds targeting cell wall biosynthesis. Determine synergy between MurB antibacterial agents and conventional antibiotics against B. anthracis and Y. pestis. Identify and validate compounds that inhibit bacterial SOS induction thereby potentiating the effects of FDA approved drugs. Select a second FDA approved drug to focus on for Burkholderia and F. Tularensis.					
Title: 8) Therapeutics Description: Toxin Therapeutics: Identify, optimize and evaluate therapeutic candidates that are effective against biological toxin agents. FY 2010 Accomplishments: Screened compound libraries utilizing a high-throughput screening system for botulinum neurotoxin (BoNT) therapeutics derived from mouse cells and embryonic stem cells. Tested and evaluated lead candidate inhibitors in relevant laboratory and animal model systems of BoNT intoxication. Performed experimental analysis to clarify the contribution of protein modification of BoNT to its structure and biochemical activity as it relates to drug development. Conducted high-throughput screening of drug libraries to identify inhibitors of ricin toxicity. FY 2011 Plans: Develop transgenic mice expressing genetically-encoded reporters of BoNT activity in neurons for use in high-throughput screening of BoNT therapeutics. Validate neurite outgrowth analysis for the identification of BoNT inhibitors. Identify host proteins responsible for BoNT light chain stabilization. Conduct co-crystallization studies of BoNT-inhibitor complexes. Perform experiments to determine toxicity and pharmacokinetics of selected ricin inhibitors. Identify host proteins involved in ricin dislocation as potential host-directed drug targets. Determine efficacy of identified ricin inhibitors in mice. FY 2012 Plans: Validate host proteins responsible for BoNT light-chain stabilization. Continue co-crystallization studies of BoNT-inhibitor complexes. Characterize host proteins that interact with BoNT and identify small molecule inhibitors preventing host-toxin interactions. Validate differential expression of host genes involved in neuron response to BoNT intoxication. Identify and develop therapies that target host proteins involved in BoNT persistence in the neuron. Validate host proteins involved in ricin			7.676	9.171	5.792

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
dislocation as potential drug targets. Continue development small molecule inhibitors to toxin threat agents (BoNT, ricin, and staphylococcal enterotoxin B).					
Title: 9) Transformational Medical Technologies Initiative Description: Multiagent (Broad Spectrum) Medical Countermeasures (MCM): Builds upon basic research performed by existing performers and supports the efforts of new performers who are in the mid-drug discovery phase of drug development. Applied research efforts also include the investigation of existing drugs to explore their efficacy against BW agents. This involves the initiation of experiments to identify markers, correlates of protection, assays, and endpoints for further non-clinical and clinical studies and development of a scalable and reproducible manufacturing process amenable to Food and Drug Administration (FDA) good manufacturing processes. FY 2010 Accomplishments: Continued efforts to evaluate novel drugs to treat HFV and ICB pathogen infections. Matured promising compounds in combination with lead therapeutic candidates. FY 2011 Plans: Continue to support new MCM discovery efforts entering the product pipeline. Continue to evaluate and mature novel drugs as post-exposure prophylaxis and treatment for HFVs and IBP infections. Identify and initiate the development of intervention strategies targeting host pathogen response, inclusive of enhancing the immune system and addressing symptoms to reduce the severity of disease.			4.105	8.037	-
Title: 10) Transformational Medical Technologies Initiative Description: Development of Platform Technologies: Platform Technologies are standalone enabling technologies that support MCM development and when strategically aligned, provide a system of systems response capability to an adverse biological event - from the identification of an unknown pathogen to the development of an approved countermeasure ready for delivery to the Warfighter and the nation. The enabling technologies are divided into five platform areas: Pathogen Characterization, Target Identification, Countermeasure Discovery, Countermeasure Evaluation, and Bioinformatics. Applied research efforts include the maturation of the components necessary to develop an integrated capability from pathogen identification and characterization to countermeasure delivery. Off-the-shelf technologies will be identified, evaluated, and where applicable, refined to demonstrate the ability to provide drug development capabilities. FY 2010 Accomplishments: Identified enabling and critical technologies, formulated appropriate technology plans and acquisition strategies, and determined their performance objectives. Initiated development of an information network to serve as the backbone for a rapid drug discovery			16.919	3.448	-

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
and development capability. Supported development of platform technologies to higher levels of maturity. Genetic sequencing studies modeled the types and quantity of data needed for the identification of unknown pathogen ID, including a genomic survey for countermeasure targets and genetic engineering. Evaluated the information network to serve as the backbone for a rapid drug discovery and development capability. Pursued informatics to support analytical activities, event response, and science discovery. Initiated work on advanced manufacturing to enhance the rapid production of therapeutics.					
FY 2011 Plans: Continue the development of host and pathogen based platforms to higher levels of maturity. Continue to explore pathogen identification and characterization capabilities, including genetic sequencing, integrate existing capabilities. Continue to assess future sequence and analysis needs to characterize advanced threats. Continue to integrate leading edge technologies with existing technologies to enhance pathogen characterization, target identification, countermeasure discovery and countermeasure evaluation platform areas.					
Title: 11) Transformational Medical Technologies Description: Multiagent (Broad Spectrum) Medical Countermeasures (MCM): Continues efforts previously funded under the Transformational Medical Technologies Initiative. It supports existing and new efforts in the drug discovery phase of drug development. Applied research efforts also include the investigation of existing drugs to explore their efficacy against BW agents. This involves the initiation of experiments to identify markers, correlates of protection, assays, and endpoints for further non-clinical and clinical studies and development of a scalable and reproducible manufacturing process amenable to Food and Drug Administration (FDA) Good Manufacturing Practices (GMP). FY 2012 Plans: Continue to support new MCM discovery efforts to refresh the Hemorrhagic Fever Virus (HFV) and Intracellular Bacterial Pathogen (IBP) product pipelines. Continue to identify and initiate the development of intervention strategies targeting host response to biological pathogens, inclusive of enhancing the immune system and treating symptoms to reduce the severity of disease.			-	-	31.084
Title: 12) Transformational Medical Technologies Description: Development of Platform Technologies: Continues efforts previously funded under the Transformational Medical Technologies Initiative. Platform Technologies are standalone enabling technologies that support MCM development and when strategically aligned, provide a system of systems response capability to an adverse biological event - from the identification of an unknown pathogen to the development of an approved countermeasure ready for delivery to the Warfighter and the nation. The enabling technologies are divided into five platform areas: Pathogen Characterization, Target Identification, Countermeasure Discovery, Countermeasure Evaluation, and Bioinformatics. Applied research efforts include the maturation of the components			-	-	5.449

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program										DATE: February 2011		
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 2: Applied Research				R-1 ITEM NOMENCLATURE PE 0602384BP: CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)				PROJECT TB2: MEDICAL BIOLOGICAL DEFENSE (APPLIED RESEARCH)				
B. Accomplishments/Planned Programs (\$ in Millions)										FY 2010	FY 2011	FY 2012
necessary to develop an integrated capability from pathogen identification and characterization to countermeasure delivery. Off-the-shelf technologies will be identified, evaluated, and where applicable, refined to demonstrate the ability to provide drug development capabilities. FY 2012 Plans: Investment to further develop host and pathogen based platforms to higher levels of maturity and fund Bio-Surveillance efforts. Continue to mature pathogen identification and characterization capabilities, including genetic sequencing, integrate existing capabilities. Continue to develop genetic sequencing and analysis technologies to characterize advanced threats. Continue integration of leading edge technologies with existing technologies to enhance pathogen characterization, target identification, countermeasure discovery and countermeasure evaluation platform areas.												
Accomplishments/Planned Programs Subtotals										54.858	43.858	84.747
C. Other Program Funding Summary (\$ in Millions)												
Line Item	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost	
• MB4: MEDICAL BIOLOGICAL DEFENSE (ACD&P)	95.483	136.975	137.653		137.653	150.128	167.604	133.589	119.626	Continuing	Continuing	
• MB5: MEDICAL BIOLOGICAL DEFENSE (SDD)	57.563	141.680	272.345		272.345	259.039	354.900	331.308	310.104	Continuing	Continuing	
• MB7: MEDICAL BIOLOGICAL DEFENSE (OP SYS DEV)	0.000	0.000	5.448		5.448	0.492	0.493	8.851	15.459	Continuing	Continuing	
• TB1: MEDICAL BIOLOGICAL DEFENSE (BASIC RESEARCH)	15.246	14.352	7.456		7.456	8.939	8.934	6.110	8.931	Continuing	Continuing	
• TB3: MEDICAL BIOLOGICAL DEFENSE (ATD)	196.007	115.233	172.636		172.636	180.913	167.900	149.413	148.398	Continuing	Continuing	
D. Acquisition Strategy												
N/A												
E. Performance Metrics												
N/A												

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program	DATE: February 2011
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APPROPRIATION/BUDGET ACTIVITY				R-1 ITEM NOMENCLATURE				PROJECT			
0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>				PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>				TC2: <i>MEDICAL CHEMICAL DEFENSE (APPLIED RESEARCH)</i>			
COST (\$ in Millions)	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost
TC2: <i>MEDICAL CHEMICAL DEFENSE (APPLIED RESEARCH)</i>	38.644	33.648	36.546	-	36.546	36.993	37.789	38.163	39.395	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project (TC2) funds applied research for the investigation of new medical countermeasures to include prophylaxes, pretreatments, antidotes, skin decontaminants and therapeutic drugs against identified and emerging chemical warfare threat agents to include a class of agents called Non Traditional Agents (NTAs). In FY11, all NTA-dedicated research was re-aligned into specific capability areas within this project in order to ensure a focused effort on this high priority area. Capability areas include: Pretreatments; pretreatments for NTAs; diagnostics; diagnostics for NTAs; therapeutics; and therapeutics for NTAs. Pretreatments includes researching prophylaxes to protect against chemical agents and NTAs. Diagnostics focuses on researching diagnostic tools that help identify exposure to chemical agents and NTAs. Therapeutics focuses on researching post-exposure countermeasures to protect against chemical agents and NTAs. Research and development efforts in this project focus on formulation and scale-up of candidate compounds.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2010	FY 2011	FY 2012
<p>Title: 1) Diagnostics</p> <p>Description: Diagnostic Technologies: Focuses on developing state-of-the-art laboratory/fieldable methods that detect exposure to chemical warfare agents (CWA) (e.g., nerve agents and vesicants) in clinical samples. Identifies biomolecular targets that can be leveraged as analytical methodologies, as well as, laboratory and animal studies characterizing time-course and longevity of a particular analyte/biomarker.</p> <p>FY 2010 Accomplishments: Continued development of definitive diagnostic biomarkers for early detection of CWA exposure using several different analytical approaches. Developed pre-symptomatic diagnostic technologies for eventual incorporation into handheld devices in order to detect CWA exposures.</p> <p>FY 2011 Plans: Continue to determine whether existing CWA biomarkers are appropriate for early detection and validation of CWA exposure in clinical samples. Determine if biomarkers that appear after exposure to sulfur mustard can be used to identify an appropriate treatment option prior to the onset of symptoms. Continue investigation of a novel surface plasmon resonance based sensor array and a phage library display to develop binding molecules as biomarkers of nerve agent exposure. All NTA-related efforts are re-aligned to Chemical Diagnostics NTA within this Budget Activity.</p> <p>FY 2012 Plans:</p>	0.711	0.865	0.929

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program			DATE: February 2011		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>		R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>		PROJECT TC2: <i>MEDICAL CHEMICAL DEFENSE (APPLIED RESEARCH)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
Complete studies of existing CWA biomarkers to determine effectiveness for early detection. Complete sulfur mustard biomarker studies for identifying pre-symptomatic treatment options. Continue investigation of a novel sensor using a phage library display.					
Title: 2) Chem Diagnostics NTA Description: Focuses on developing state-of-the-art laboratory/fieldable methods to detect exposure to non-traditional agents in clinical samples. Identifies biomolecular targets that can be leveraged as analytical methodologies, as well as, laboratory and animal studies characterizing time-course and longevity of a particular analyte/biomarker. Non-NTA Chem Diagnostics support the analytics for traditional agent diagnostics and hand-held diagnostic technologies that might be applied to NTA diagnostics. FY 2011 Plans: Continue studies to identify biomarkers to create an enhanced capability to pre-symptomatically diagnose NTA exposure. Continue method development for identification and validation of NTAs in clinical samples. FY 2012 Plans: Further identify biomarkers to create an enhanced capability to pre-symptomatically diagnose NTA exposure. Continue method development for identification and validation of NTAs in clinical samples. Initiate method development for identification and validation of NTAs in clinical samples for additional compounds of interest.			-	0.400	0.579
Title: 3) Pretreatments Description: Nerve Agent, Pretreatments: Develops pretreatments that provide protection against all organophosphorous nerve agents. Enzymes should have the ability to rapidly bind and detoxify nerve agents, and have broad binding specificity and high enzymatic efficiency for the destruction of agents. FY 2010 Accomplishments: Developed formulations for improved and reduced immune system stimulation of stoichiometric enzymes, with a particular focus on providing protection against Non-Traditional Agents (NTAs). Investigated improved drug-delivery systems for 1st generation stoichiometric enzymes. Conducted supportive studies toward licensure of stoichiometric enzymes. FY 2011 Plans: Further refine methods and expression systems for screening, production and purification of designed catalytic bioscavengers. Initiate development of animal expression systems for delivery of newly designed improved catalytic bioscavengers. Initiate efficacy studies of small molecule approaches towards acetylcholinesterase AChE protection. All NTA-related efforts are re-aligned to Chemical Pretreatments NTA within this Project. FY 2012 Plans:			8.057	5.980	6.670

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program			DATE: February 2011		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>		R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>		PROJECT TC2: <i>MEDICAL CHEMICAL DEFENSE (APPLIED RESEARCH)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
Utilize novel methods to develop candidate proteins capable of destroying CWAs. Assess processes to produce, screen, and purify newly designed enzymes. Evaluate efficacy of small molecule approaches toward AChE protection.					
Title: 4) Chem Pretreatments NTA Description: Develops pretreatments that provide protection against non-traditional agents. Enzymes should have the ability to rapidly bind and detoxify nerve agents, and have broad binding specificity and high catalytic efficiency for the destruction of agents. FY 2011 Plans: Continue efforts to investigate ways to decrease the development time to deliver a bioscavenger (stoichiometric/catalytic) to protect the Warfighter. Continue studies to determine efficacy of bioscavenger for all NTA exposure. FY 2012 Plans: Determine efficacy of enzyme candidates for all NTA exposure.			-	1.500	3.355
Title: 5) Therapeutics Description: Cutaneous and Ocular: Focuses on therapeutic strategies to effectively minimize injuries to dermal (i.e., skin) and ocular tissues resulting from exposure to chemical warfare agents (CWAs). Involves the development of effective practical field and clinic management strategies and physical and pharmacological interventions to treat the injury processes. This work is designed to develop potential candidates that will ultimately be submitted for FDA licensure or new indications for previously licensed products for use in the treatment of chemical warfare casualties. FY 2010 Accomplishments: Continued to determine the efficacy of bioengineering and molecular biology approaches to treat sulfur mustard ocular injury. Continued testing of cell-based approaches to facilitate blister agent wound healing. Continued development of a decontaminant for penetrating wounds containing CWAs. Maintain effort to determine the chronic consequences of blister agent exposure. Began novel efforts to increase drug delivery of candidate countermeasures. Enhanced current anti-inflammatory approaches to treating blister agent injury. Evaluated the commonality in mechanisms of blister-induced injury across tissues and routes of exposure. FY 2011 Plans: Continue development of novel drug delivery approaches for candidate countermeasures. Continue to determine the effectiveness of multiple anti-inflammatory approaches in vitro against blister agent exposure. Continue investigation of potential therapeutic approaches to mitigate the chronic effects of blister agent exposure. FY 2012 Plans:			3.946	1.275	1.256

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program			DATE: February 2011		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>		R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>		PROJECT TC2: <i>MEDICAL CHEMICAL DEFENSE (APPLIED RESEARCH)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
Further evaluate the effectiveness of multiple anti-inflammatory approaches in vitro and in vivo against sulfur mustard exposure. Continue to develop molecular biology approaches to assess candidate countermeasures against skin and eye injury caused by sulfur mustard. Further evaluate most effective therapeutic approaches to mitigate the chronic effects of sulfur mustard exposure.					
Title: 6) Therapeutics Description: Neurologic: Focuses on therapeutic strategies to effectively minimize neurologic injuries resulting from exposure to CWAs. This effort involves the development of neuroprotectants, anticonvulsants, and improved neurotransmitter restorers. This work is designed to develop potential candidates that will ultimately be submitted for FDA licensure or new indications for previously licensed products for use in the treatment of chemical warfare casualties. FY 2010 Accomplishments: Identified and developed drug-delivery systems to improve the restoration of nerve transmitters following exposure to chemical agents. Utilized structure-activity relationships to identify anticholinergic drugs with reduced side effects and novel neuroprotectants and anti-epileptics to protect against nerve agents. FY 2011 Plans: Continue to investigate the mechanism of reactivation of nerve-agent inhibited acetylcholinesterase (AChE) in order to identify or design compounds that allow for a longer time frame between exposure and the administration of the therapeutic without decreasing its effectiveness. Continue to explore approaches for neuroprotection against nerve agent exposure. Develop therapeutic strategies to effectively minimize neurologic injuries resulting from exposure to CWAs by testing in silico and in vitro. FY 2012 Plans: Utilizing mechanistic understanding of reactivation, identify compounds capable of reactivating nerve-agent inhibited AChE at delayed times after exposure. Identify more effective approaches for neuroprotection, as defined by the minimization of chronic functional decrement due to nerve agent exposure. Conduct in silico and in vitro evaluation of novel and/or Food and Drug Administration licensed products for treatment of acute nerve agent exposure. Investigate systems biology approaches for nerve agent therapeutics.			10.830	7.840	10.787
Title: 7) Therapeutics Description: Medical Toxicology (Non Traditional Agents (NTAs) and Other Agents): Investigates common mechanisms of agent injury. Determines the toxic effects of agents by probable routes of field exposure, as well as standard experimental routes. Physiological parameters and pathological assessment will be used to establish the general mode and mechanism(s) of toxicity. In FY11, all NTA-related efforts are re-aligned to Chemical Therapeutics NTA within this Project. FY 2010 Accomplishments:			6.200	-	-

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program			DATE: February 2011		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>		R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>		PROJECT TC2: <i>MEDICAL CHEMICAL DEFENSE (APPLIED RESEARCH)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2010	FY 2011	FY 2012
Investigated and studied receptor effects of common and agent-specific mechanisms of NTA injury for therapeutic intervention.					
Title: 8) Therapeutics Description: Respiratory and Systemic: Supports investigation of the systemic host response to chemical warfare agent (CWA) injury via all routes of exposure, with emphasis on the respiratory system and chronic effects of exposure. This involves the development of effective practical field and clinic management strategies and physical and pharmacological interventions to treat the injury processes. This work is designed to support eventual Food and Drug Administration (FDA) licensure of new compounds or new indications for licensed products for use in the treatment of chemical warfare casualties. FY 2010 Accomplishments: Evaluated safety, efficacy, dosing and relevant effects on the body, and the body's effects on the drug, of candidate countermeasures against lung injury. Investigated down-selected potential candidate countermeasures based on molecular biology approaches to CWA lung injury. Continued to study long-term health effects due to CWA exposure. FY 2011 Plans: Continue to evaluate safety, efficacy, dosing and relevant effects on the body, and the body's effects on the drug, of candidate countermeasures against lung injury. Continue to investigate down-selected potential candidate countermeasures based on molecular biology approaches to CWA lung injury. Continue to study long-term health effects due to CWA exposure.			2.700	2.788	-
Title: 9) Therapeutics Description: Therapeutics for Non Traditional Agents (NTAs): Develops, assesses, evaluates, and validates therapeutics for treatment resulting from exposure to NTAs. In FY11, all NTA-related efforts are re-aligned to Chemical Therapeutics NTA within this Project. FY 2010 Accomplishments: Further developed and validated animal models for testing clinical efficacy of therapeutics against NTAs. Identified binding characteristics of NTAs, as well as mitigated NTA toxicity by researching and developing novel therapeutics.			6.200	-	-
Title: 10) Chem Therapeutics NTA Description: Investigates common mechanisms of agent injury. Determines the toxic effects of agents by probable routes of field exposure, as well as standard experimental routes. Physiological parameters and pathological assessment will be used to establish the general mode and mechanism(s) of toxicity. Develops, assesses, evaluates, and validates therapeutics for treatment resulting from exposure to Non-Traditional Agents (NTA). FY 2011 Plans:			-	13.000	12.970

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program										DATE: February 2011		
APPROPRIATION/BUDGET ACTIVITY 0400: <i>Research, Development, Test & Evaluation, Defense-Wide</i> BA 2: <i>Applied Research</i>				R-1 ITEM NOMENCLATURE PE 0602384BP: <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>				PROJECT TC2: <i>MEDICAL CHEMICAL DEFENSE (APPLIED RESEARCH)</i>				
B. Accomplishments/Planned Programs (\$ in Millions)										FY 2010	FY 2011	FY 2012
Continue binding studies to support the design and synthesis of an improved reactivator. Continue evaluation of improved products to treat NTA exposure. Continue investigation of pathophysiological effects to identify debilitating syndromes caused by exposure to NTAs. Continue development of animal models for various routes of exposure to NTA. These models will be utilized to evaluate toxic effects of NTAs, behavioral changes, efficacy, and FDA animal rule approvals.												
FY 2012 Plans: Continue binding studies to support the design and synthesis of an improved reactivator. Continue evaluation of improved products to treat NTA exposure. Continue investigation of pathophysiological effects to identify debilitating syndromes caused by exposure to NTAs. Continue development of animal models for various routes of exposure to NTA. Conduct in silico and in vitro evaluation of novel and/or Food and Drug Administration licensed products for treatment of NTA exposure. Study mechanisms of NTA injury for therapeutic intervention.												
Accomplishments/Planned Programs Subtotals										38.644	33.648	36.546
C. Other Program Funding Summary (\$ in Millions)												
Line Item	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost	
• TC1: <i>MEDICAL CHEMICAL DEFENSE (BASIC RESEARCH)</i>	6.027	3.144	0.000		0.000	0.000	0.000	0.000	0.000	0.000	9.171	
• TC3: <i>MEDICAL CHEMICAL DEFENSE (ATD)</i>	28.046	29.134	21.582		21.582	21.900	22.695	23.193	23.919	Continuing	Continuing	
D. Acquisition Strategy N/A												
E. Performance Metrics N/A												

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program **DATE:** February 2011

APPROPRIATION/BUDGET ACTIVITY				R-1 ITEM NOMENCLATURE				PROJECT			
0400: Research, Development, Test & Evaluation, Defense-Wide BA 2: Applied Research				PE 0602384BP: CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)				TR2: MEDICAL RADIOLOGICAL DEFENSE (APPLIED RESEARCH)			
COST (\$ in Millions)	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost
TR2: MEDICAL RADIOLOGICAL DEFENSE (APPLIED RESEARCH)	1.818	2.884	0.806	-	0.806	0.605	0.603	0.379	0.335	Continuing	Continuing

A. Mission Description and Budget Item Justification

This project (TR2) funds applied research to develop medical countermeasures to protect the Warfighter against acute radiological exposure. Specifically, innovative technical approaches will be used to develop products to mitigate health consequences resulting from Acute Radiation Exposure (ARS) and Delayed Effects of Acute Radiation Exposure (DEARE). The research and development of medical countermeasures for radiation exposure will ultimately enhance the survivability of Warfighters and will serve to significantly minimize the development of acute radiation syndromes and subsequent health problems. Results of efforts funded under this project are collaboratively shared with other government agencies, while the Department of Defense maintains an emphasis on the development of pretreatments to protect military personnel who could be involved in responding to a radiological incident.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2010	FY 2011	FY 2012
Title: 1) Radiological Medical Countermeasures Description: Radiation Medical Countermeasures: Develop medical countermeasures to protect the Warfighter against acute radiological/nuclear exposure, to include developing both pretreatments (prophylaxis) and post-irradiation therapeutics against radiological/nuclear exposure. DoD is the only governmental agency currently developing medical prophylaxis to protect Warfighters and/or other responders in the event of a radiological incident. FY 2010 Accomplishments: Evaluated mature and promising drug candidates for respiratory and gastrointestinal damage and repair, demonstrating efficacy, safety, and animal (rodents) survival exposed to lethal radiation for a future non-human primate (NHP) efficacy study. Identified common biochemical/physiological mechanisms for hematological, respiratory and gastrointestinal damage and repair, as well as, biology of cellular damage. FY 2011 Plans: Continue to evaluate novel and FDA-approved drugs for efficacy against radiation exposure maintaining a focus on potential mechanisms of action. These studies will help identify biochemical/physiological mechanisms that could be exploited for expanding the scope of potential therapeutic approaches. Continue to focus approaches on the GI and lung injury related to radiation exposure. Continue evaluation and identification of unique, novel and promising biomarkers useful for biodosimetry and potential pathways for therapeutic approaches. FY 2012 Plans:	1.818	2.884	0.806

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Exhibit R-2A, RDT&E Project Justification: PB 2012 Chemical and Biological Defense Program										DATE: February 2011		
APPROPRIATION/BUDGET ACTIVITY 0400: Research, Development, Test & Evaluation, Defense-Wide BA 2: Applied Research				R-1 ITEM NOMENCLATURE PE 0602384BP: CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)				PROJECT TR2: MEDICAL RADIOLOGICAL DEFENSE (APPLIED RESEARCH)				
B. Accomplishments/Planned Programs (\$ in Millions)										FY 2010	FY 2011	FY 2012
Further evaluate novel biomarkers useful for biodosimetry and identification of potential therapeutic approaches. Reduction in funds reflect changing priorities in the development of medical countermeasures.												
Accomplishments/Planned Programs Subtotals										1.818	2.884	0.806
C. Other Program Funding Summary (\$ in Millions)												
Line Item	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost	
• TR1: MEDICAL RADIOLOGICAL DEFENSE (BASIC RESEARCH)	0.925	0.971	0.000		0.000	0.000	0.000	0.000	0.000	0.000	1.896	
• TR3: MEDICAL RADIOLOGICAL DEFENSE (ATD)	4.086	0.957	0.000		0.000	0.200	0.200	0.434	0.484	Continuing	Continuing	
D. Acquisition Strategy												
N/A												
E. Performance Metrics												
N/A												

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